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EXAMINER	
TSAY, MARSHA M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,354	SCHULZ ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received December 26, 2007. Claims 1-20 are pending and currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is August 12, 2003.

Objections and Rejections

Claim 4 is objected to because of the following informalities: in claim 4, line 4, the term "Triton" should be corrected to "Triton X-100". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 12 has currently been amended to include the limitation, wherein the active form of A1AT has a maximum activity of 100%. Applicants point to Figure 1 for support of this

limitation. Applicants submit that the SDS-PAGE shows A1AT which corresponds to the band slightly above 50 kD when compared to the molecular weight marker in line 1. This band indicates that the A1AT isolated is the same as native plasma and, thus, figure 1 shows that the A1AT containing solution of the claimed invention does not influence the ratio of active/inactive A1AT of native plasma. Applicants submit that it would be apparent to one of ordinary skill that the maximal activity of the active form of A1AT is 100%. This is not found convincing because it is unclear how one of ordinary skill would find it apparent that the maximal activity of A1AT is 100% based on a SDS-PAGE indicating that A1AT has a MW of 50 kD. It is known in the art that in plasma, A1AT has an active and an inactive isomer (Mattes et al.). One of ordinary skill would recognize that while isomers of a compound and/or molecule differ structurally but have the same molecular formula, and therefore, the same MW. Therefore, if both isomers of A1AT have the same MW, it is unclear how it is apparent from Fig. 1, that the maximal activity of the active form of A1AT is 100%. It is unclear how the instant specification has support for said limitation, i.e. wherein the active form of A1AT has a maximum activity of 100%.

Claims 1-5, 9-11, 13-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for purifying A1AT at concentrations and conditions including 0.1% (w/w) Triton and Tween 80, 0.03% (w/w) tri-n-butyl phosphate, 0.1 mM caprylic or caprylate, an incubation time of 0.1 hours (claim 4), a salt concentration of 0.5 M (claim 5), pasteurization in the presence of 0.5 M sodium citrate (claim 8), an incubation temperature at 15°C (claim 13e), does not reasonably provide enablement said process at concentrations and conditions including >0.1% (w/w) Triton and Tween 80, >0.03% (w/w) tri-n-

butyl phosphate, >0.1 mM caprylic or caprylate, an incubation time of >0.1 hours (claim 4), a salt concentration of >0.5 M (claim 5), pasteurization in the presence of >0.5 M sodium citrate (claim 8), an incubation temperature at >15°C (claim 13e). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain which concentrations, incubation time, and temperatures greater than the values noted above will allow a functionally active A1AT to be purified. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly which values above >0.1% (w/w) Triton and Tween 80, >0.03% (w/w) tri-n-butyl phosphate, >0.1 mM caprylic or caprylate, an incubation time of >0.1 hours (claim 4), a salt concentration of >0.5 M (claim 5), pasteurization in the presence of >0.5 M sodium citrate (claim 8), an incubation temperature at >15°C (claim 13e) will allow the purification of an A1AT having a purity >90% and an activity of ≥0.8 PEG/mg in its active form.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of

experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large since any value >0.1% (w/w) Triton and Tween 80, >0.03% (w/w) tri-n-butyl phosphate, >0.1 mM caprylic or caprylate, an incubation time of >0.1 hours (claim 4), a salt concentration of >0.5 M (claim 5), pasteurization in the presence of >0.5 M sodium citrate (claim 8), an incubation temperature at >15°C (claim 13e) can be chosen. The amount of guidance is minimal with regard to which values above the base conditions will result in the purification of a functional A1AT having a purity >90% and an activity of $\geq$0.8 PEG/mg in its active form. In Example 1 of the specification (p. 11-12), Applicants disclose a solvent/detergent treatment comprising using 1% (w/w)Triton X-100, 0.3% (w/w) tri-n-butyl phosphate, for 4 hours at 20°C, and a salt concentration of 1.5M sodium citrate. The nature of the invention is such that a change in the concentration of the salt solution, detergents, incubation period, and/or temperature may disrupt the structure and therefore, the activity of the protein (A1AT). The state of the prior art is that proteins are sensitive to their environment and any changes to their physical environment may disrupt their activity. The relative level of skill in this art is very high. The predictability as to

which values >0.1% (w/w) Triton and Tween 80, >0.03% (w/w) tri-n-butyl phosphate, >0.1 mM caprylic or caprylate, an incubation time of >0.1 hours (claim 4), a salt concentration of >0.5 M (claim 5), pasteurization in the presence of >0.5 M sodium citrate (claim 8), an incubation temperature at >15°C (claim 13c) will confer a functional A1AT having a purity >90% and an activity of ≥0.8 PEG/mg in its active form is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the preamble recites a process for purifying A1AT from A1AT containing solutions from other protein components. It is unclear if it is "A1AT" being purified or if it is "A1AT containing solution" being purified. Further, the preamble recites "solutions" (plural), but step 1(a) recites "solution" (singular). Clarification and correction are required.

Claims 8, 14 recite the phrase "wherein a further virus inactivation step is performed afterwards". It is unclear which step is meant by "afterwards" and therefore, it is unclear after which step the virus inactivation step is performed. Further clarification is requested. Also, claim 8 recites the phrase "afterwards, the virus inactivation step" does not make sense. Claims

5 or 1 (from which claim 8 depends from) do not recite any virus inactivation steps. Clarification is requested.

Claim 13 recites the optional steps (c) and (d). Since the steps are noted as being optional, it is unclear if steps (c) and (d) are sequential or if each could occur in a different order after step (b). Further clarification is requested.

Claims 2-7, 9-12, 15-20 are included in this rejection because they are dependent on the above claims and fail to cure the defect.

Applicants' amendment has overcome some of the previous 35 U.S.C. 112, second paragraph, indefinite issues. However, some indefinite issues still remain, as noted above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mattes et al. (AU 199874180 B2; IDS as WO9856821). Claims 12-19 are drawn to an A1AT protein composition. Mattes et al. teach a purified A1AT protein product (p. 24 Table 2). The purified A1AT product obtained by the method of Example 2 has a purity of >90% (~118%) and has a specific activity of ≥0.8 PEU/mg (~1.0 PEU/mg) (p. 24; claims 12-18, 20). Mattes et al. also teach the A1AT composition can be prepared as a solution or a lyophilized preparation as well as a method of preparing such a composition (p. 26 claim 11; claims 17-18).

While Mattes et al. do not explicitly teach the elements of an IgA content ≤1 mg/mL, a residual detergent of <50 ppm, or a monomer content of >90%, these elements are believed to be anticipated by Mattes et al. since the A1AT protein product of Mattes et al. already meets the instant elements of having a purity >90% (~118%), it would inherently not contain additional protein components or residual detergents, and since it has a specific activity of ≥0.8 PEU/mg (~1.0 PEU/mg), it would inherently have a monomer content of >90%. Instant claims 13-17 are dependent on the A1AT product of claim 12 and recite the process on how it is obtained. However, the method steps recited in claims 13-17 do not change the A1AT protein product, i.e. they are still drawn to an A1AT protein having a purity of >90% and a specific activity of ≥0.8 PEU/mg. Since Mattes et al. teach an A1AT protein product that meets the limitations of claim 12, claims 13-17 are also anticipated by Mattes et al. because they are drawn to the same product.

In their remarks, Applicants assert that claim 12 has been amended to recite that the "active form of A1AT has a maximum activity of 100%." Applicants assert that this claimed feature is show in figure 1 of the specification which illustrates the results of a SDS-PAGE of A1AT solutions. According to Applicants, this electropherogram shows A1AT which corresponds to the band slightly above 50 kD when compared to the molecular weight marker in line 1. This band indicates that the A1AT isolated is the same as native plasma and, thus, figure 1 shows that the A1AT containing solution of the claimed invention does not influence the ratio of active/inactive A1AT of native plasma. In contrast, Mattes et al. disclose a method of preparation with A1AT having an activity of at least 120%. Applicants assert that this increased

activity results from a greater ratio of active to inactive A1AT in the preparation than is present in plasma (abstract Mattes et al.). Applicant's arguments have been fully considered but they are not persuasive.

Claim 12 has currently been amended to include the limitation that the active form of A1AT has a maximum activity of 100%. Firstly, it is unclear how Applicants concluded that based on the SDS-PAGE show in figure 1, that the instant purified A1AT with a MW of 50 kD has a maximal activity of 100%. Mattes et al. disclose that in plasma, A1AT occurs both in an active as well as an inactive form (p. 4). Mattes et al. further disclose that the relative plasma A1AT activity is defined as the ratio of active to inactive isomers of A1AT (p. 5-9). One of ordinary skill would recognize that while isomers of a compound and/or molecule differ structurally but have the same molecular formula, and therefore, the same MW. Since it is unclear how Applicants can determine the instant maximum activity of the A1AT recited in claim 12, the instant claim remains rejected under Mattes et al. because Mattes et al. teach a A1AT protein having a purity >90% (~118%), which would inherently not contain additional protein components or residual detergents, and a specific activity $\geq$0.8 PEU/mg (~1.0 PEU/mg), which would therefore, inherently have a monomer content of >90%.

Claims 1-5, 9-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al. (US 6284874). Taniguchi et al. teach a method of purifying alpha-1 proteinase inhibitor, also known as α_1-antitrypsin (A1AT), by flow-through chromatography, viral inactivation, and filtration (col. 2-4). In Example 1, Taniguchi et al. teach a plasma fraction of IV_1+IV_4 was solubilized in PEG/$ZnCl_2$, applied to a QAE anionic-exchange chromatographic

column (col. 6 lines 60-65; claim 1a), eluted, and diafiltered (col. 7 lines 1-10). Taniguchi et al. further teach that 1.1 kg of a detergent solution of 10% w/v polysorbital 80 and 3% w/v tri-n-butyl phosphate (TnBP) was added to the diafiltered A1AT and incubated at 25°C for 1 hr. to inactivate any viral contaminants (col. 7 lines 10-15; claim 1b). The A1AT solution was then applied to a copper chelating medium and washed with 150 mM NaCl, 500 mM NaCl (col. 7 lines 20-25; claim 1c). The A1AT solution was the ultrafiltered, filtrate was collected, and diafiltered by ultrafiltration against 50 mM NaCl (col. 7 lines 30-35; claim 5, 9). Taniguchi et al. teach the filter used has a 100 kD MWCO, which is in the range of a filter having a pore size between 15-20 nm (col. 5 line 31-32; claim 10).

In their remarks, Applicants assert that the claimed method of purifying involves salting the detergents out after treatment (e.g. applying the salt to the elution of the ion-exchange chromatography), as disclosed in Example 1. In contrast, Taniguchi et al. apply NaCl solutions for washing the medium prior to use. Thus, Taniguchi et al. do not anticipate claims 1-5, 9-11. Applicant's arguments have been fully considered but they are not persuasive.

Claims 1-5, 9-11 are drawn to a process for purifying A1AT from A1AT solutions comprising the steps as recited in the claims. The use of open language "comprising" allows for the inclusion of other unspecified steps and/or ingredients in the claim interpretation. Therefore, while Taniguchi et al. teach applying NaCl solution to the A1AT solution prior to ion-exchange chromatography, Taniguchi et al. also teach the applying NaCl solution to the A1AT protein solution after ion-exchange chromatography (col. 7 lines 5-35). For these reasons, the instant claims remain rejected under Taniguchi et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (US 6284874) in view of Isaksson et al. (WO 9426287; IDS). The teachings of Taniguchi et al. are outlined above. Taniguchi et al. do not teach a heparin gel or a pasteurization step.

Isaksson et al. teach a process for reduction of virus inactivating chemicals and/or detergents in an aqueous composition containing a water-soluble plasma protein (abstract). Isaksson et al. further teach that when the aqueous base comprises a salt of citrate at >1 M, the virus inactivating chemical or detergent can give a final concentration below 5 ppm (abstract). Isaksson et al. teach the method is applicable to any plasma protein (p. 6 lines 15-20). In example I, Isaksson et al. teach the plasma protein antithrombin III (AT III) was separated from plasma by using a heparin sepharose gel (p. 7 lines 15-18). Isaksson et al. further teach an additional virus inactivation step of incubating the plasma protein solution in 2 M sodium citrate (p. 7 lines 20-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Taniguchi et al. by substituting the heparin sepharose gel of Isaksson et al. for the anionic-exchange column used in Taniguchi et al. (claims 6-7). One of ordinary skill would recognize that the chromatographic step can be substituted with a functionally equivalent column that is commercially available and would expect to have a

reasonable level of success in using a heparin sepharose gel to isolate A1AT because Isaksson et al. disclose its success application in separating another plasma protein.

It would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Taniguchi et al. by including the additional virus inactivation step of Isaksson et al. to the A1AT purification process of Taniguchi et al. (claim 8). The motivation to do so is given by Isaksson et al. which disclose that sodium citrate helps in reducing the residual detergent content and therefore, would result in a purer protein product.

In their remarks, Applicants assert that Taniguchi et al. does not discuss "salting out" of the detergents according to the instant claims.

The Taniguchi et al. reference is relevant art and is maintained for the reasons noted above.

Applicants further assert that Isaksson et al. disclose the removal of detergents using a sodium citrate method but its final product is medically unacceptable because, as seen in Example 4, it comprises 250 ppm Triton X-100 and 35 ppm TnBP. Applicant's arguments have been fully considered but they are not persuasive.

The Isaksson et al. reference was used to remedy the Taniguchi et al. reference because the Taniguchi et al. reference does not teach a virus inactivation step. Isaksson et al. disclose that the virus inactivation step can be applied, in general, to water-soluble plasma proteins, i.e. factor VIII, factor IX, albumin, alpha1-acid glycoprotein. It is known in the art that A1AT is a plasma protein (Mattes et al.). In Examples 1-4, Isaksson et al. disclose non-limiting examples of applying a virus inactivation step to proteins (antithrombin III, transferring, albumin)

isolated/purified by different processes (p. 7-9). In Example 1, the AT III is separated from plasma by Heparin Sepharose gel; in example 2, the transferring is isolated in "Cohn's cold ethanol method" followed by chromatography; in example 3, the AT III is isolated by sepharose gel; and in example 4, the albumin is isolated by a modified "Cohn's cold ethanol method." Applicants assert that Isaksson et al. disclose the removal of detergents using a sodium citrate method but its final product is medically unacceptable because, as seen in Example 4, it comprises 250 ppm Triton X-100 and 35 ppm TnBP. One of ordinary skill would recognize that the higher detergent concentration in example 4 is due to the lack of an additional chromatographic step, and not the virus inactivation step (see Example 2 vs. Example 4). Therefore, depending on the isolation/purification process used to purify the plasma protein, one of ordinary skill would recognize that the virus inactivation step of Isaksson et al. would only help in reducing residual detergent content and result in a purer protein product.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mattes et al. (AU 199874180 B2; IDS as WO9856821). Mattes et al. disclose A1AT deficiencies include degenerative lung disease, i.e. emphysema (p. 4). As noted above, Mattes et al. disclose an A1AT protein having a purity of >90% and a specific activity of $\geq$0.8 PEU/mg. Mattes et al. do not explicitly teach a method of treating a degenerative lung phenomena of the lung comprising administering A1AT to a subject in need thereof.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the A1AT of Mattes et al. to a subject for treating a degenerative lung disease because Mattes et al. disclose A1AT deficiency is associated with degenerative lung

disease and it would be reasonable for one of ordinary skill to expect that administering an A1AT protein having a purity of >90% and a specific activity of ≥0.8 PEU/mg would be successful in overcoming the A1AT deficiency since their is a direct correlation between plasma level of functional A1AT to lung disease (claim 19).

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

March 12, 2008